



Kairos Pharma Reports Positive, Statistically Significant Interim Efficacy Data from Phase 2 Trial of ENV-105 in Metastatic Prostate Cancer

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LOS ANGELES--(BUSINESS WIRE)-- Kairos Pharma, Ltd. (NYSE American: KAPA), a clinical-stage biopharmaceutical company addressing drug resistance in cancer, today announced positive interim efficacy data from its ongoing Phase 2 clinical trial evaluating ENV-105 (carotuximab) in combination with apalutamide in patients with metastatic castration-resistant prostate cancer (mCRPC). The interim analysis demonstrated a statistically significant difference in progression-free survival (PFS) between all patients in the trial treated with ENV-105 plus apalutamide and those treated with apalutamide alone. Median PFS was 17.7 months with the combination compared with 2 months with apalutamide alone ($P=0.0008$).

With the interim efficacy signal, Kairos Pharma has modified the Phase 2 protocol to enroll patients earlier in the course of disease progression. Rather than treating patients after one or two anti-androgen agents, the modified protocol will enroll patients who experience a PSA increase following upfront treatment with an androgen signaling inhibitor. Patients will be randomized to enzalutamide alone or enzalutamide in combination with ENV-105. The protocol modification is intended to expand the eligible patient population and facilitate enrollment, with Kairos Pharma targeting completion of the Phase 2 trial in or before the fourth quarter of 2027.

"These interim results provide an important clinical signal for ENV-105 and support our strategy of targeting the mechanisms underlying drug resistance," said Kairos Pharma Chief Executive Officer Dr. John Yu. "The protocol modification will allow more patients to be eligible for the potential benefits of ENV-105 treatment while evaluating the therapy earlier in disease progression."

The findings further support Kairos Pharma's strategy of targeting mechanisms associated with cancer drug resistance. ENV-105 targets CD105, a protein identified as a key driver of resistance and disease relapse in response to standard therapy, providing the rationale for evaluating ENV-105 in combination with standard cancer therapies. The Phase 2 trial is designed to evaluate ENV-105, a first-in-class CD105 antibody, in men with metastatic prostate cancer resistant to standard hormone therapy, in combination with standard of care, apalutamide. Patients have been enrolled at Cedars-Sinai Medical Center, City of Hope and Huntsman Cancer Institute at the University of

Utah.

About Kairos Pharma Ltd.

Based in Los Angeles, California, Kairos Pharma Ltd. (NYSE American: KAPA) is at the forefront of oncology therapeutics, utilizing structural biology to overcome drug resistance and immune suppression in cancer. Kairos Pharma's lead candidate, ENV-105 (carotuximab), is an antibody targeting CD105 — a protein identified as a key driver of resistance and disease relapse in response to standard cancer therapy. ENV-105 aims to reverse drug resistance by targeting CD105 and restore the effectiveness of standard therapies across multiple cancer types. For more information, visit kairospharma.com.

Cautionary Statement Concerning Forward-Looking Statements

This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995. Forward-looking statements are identified by terminology such as "may," "should," "expects," "anticipates," "contemplates," "estimates," "believes," "plans," "projected," "predicts," "potential," or "hopes," or the negative of these or similar terms. Actual results could vary materially from expectations and projections of Kairos Pharma if underlying assumptions prove inaccurate or if known or unknown risks or uncertainties materialize. Risk factors include but are not limited to: success and/or completion of Phase 2 clinical trials (for prostate cancer) and Phase 1 clinical trials (for lung cancer); challenges inherent in product research and development; uncertainty regarding future regulatory approval and commercial success; and other factors described in Kairos Pharma's SEC filings, including its Annual Report on Form 10-K and Quarterly Reports on Form 10-Q. Kairos Pharma is not obligated to update any forward-looking statement except as required by applicable law.

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